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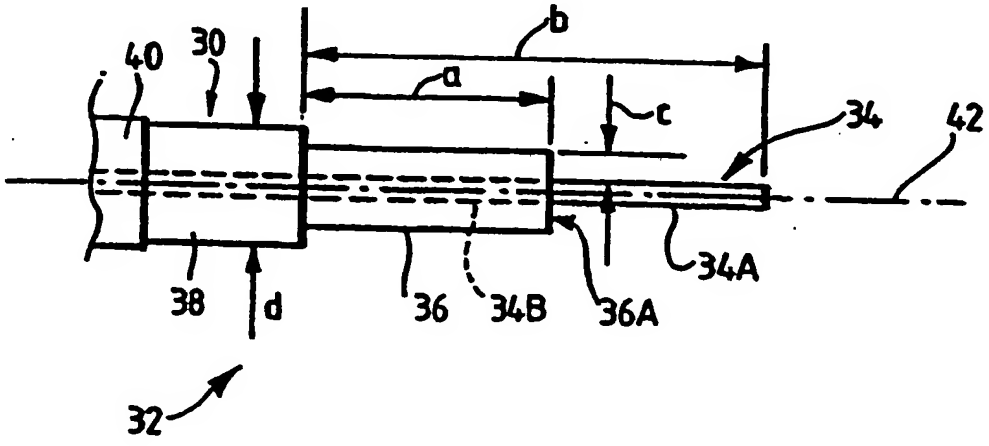
(54) Title: AN ELECTROSURGICAL INSTRUMENT



(57) Abstract

In an electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium (e.g. "underwater surgery") a bipolar electrode assembly has an active electrode having an exposed tissue treatment portion (34A), a return electrode (38) having an exposed fluid contact surface, and an insulating member (36) positioned between and electrically insulating the active electrode in the return electrode. The insulating member serves to space apart the exposed active electrode treatment portion and the exposed fluid contact portion of the return electrode. The dimensions and configurations of the exposed portions of the electrodes and of the insulating member are such that when the electrode assembly is immersed in a conductive fluid medium, the ratio between the longest and shortest conduction path lenghts between the active and return (b:a) electrodes is less than or equal to 2:1. The invention also includes a combination of an electrosurgical instrument and a radio frequency generator.

AN ELECTROSURGICAL INSTRUMENT

This invention relates to an electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium, and to an electrosurgical system apparatus including such an instrument.

Endoscopic electrosurgery is useful for treating tissue in cavities of the body, and is normally performed in the presence of a distension medium. When the distension medium is a liquid, this is commonly referred to as underwater electrosurgery, this term denoting electrosurgery in which living tissue is treated using an electrosurgical instrument with a treatment electrode or electrodes immersed in liquid at the operation site. A gaseous medium is commonly employed when endoscopic surgery is performed in a distensible body cavity of larger potential volume in which a liquid medium would be unsuitable, as is often the case in laparoscopic or gastroenterological surgery.

Underwater surgery is commonly performed using endoscopic techniques, in which the endoscope itself may provide a conduit (commonly referred to as a working channel) for the passage of an electrode. Alternatively, the endoscope may be specifically adapted (as in a resectoscope) to include means for mounting an electrode, or the electrode may be introduced into a body cavity via a separate access means at an angle with respect to the endoscope - a technique commonly referred to as triangulation. These variations in technique can be subdivided by surgical speciality, where one or other of the techniques has particular advantages given the access route to the specific body cavity. Endoscopes with integral working channels, or those characterised as resectoscopes, are generally employed when the body cavity may be accessed through a natural body opening - such as the cervical canal to access the endometrial cavity of the uterus, or the urethra to access the prostate gland and the bladder. Endoscopes specifically designed for use in the endometrial cavity are referred to as hysteroscopes, and those designed for use in the urinary tract include cystoscopes, urethroscopes and resectoscopes. The procedures of transurethal resection or vaporisation of the prostate gland are known as TURP and EVAP respectively. When there is no natural body opening through which an endoscope may

namely that the ratio of the contact areas of the return electrode and of the active electrode is greater than 7:1 and smaller than 20:1 for cutting purposes. This range relates only to cutting electrode configurations. When a bipolar instrument is used for desiccation or coagulation, the ratio of the contact areas of the two electrodes may be reduced to approximately 1:1 to avoid differential electrical stresses occurring at the contact between the tissue and the electrode.

The electrical junction between the return electrode and tissue can be supported by wetting of the tissue by a conductive solution such as normal saline. This ensures that the surgical effect is limited to the needle or active electrode, with the electric circuit between the two electrodes being completed by the tissue. One of the obvious limitations with the design is that the needle must be completely buried in the tissue to enable the return electrode to complete the circuit. Another problem is one of the orientation: even a relatively small change in application angle from the ideal perpendicular contact with respect to the tissue surface, will change the contact area ratio, so that a surgical effect can occur in the tissue in contact with the return electrode.

Cavity distension provides space for gaining access to the operation site, to improve visualisation, and to allow for manipulation of instruments. In low volume body cavities, particularly where it is desirable to distend the cavity under higher pressure, liquid rather than gas is more commonly used due to better optical characteristics, and because it washes blood away from the operative site.

Conventional underwater electrosurgery has been performed using a non-conductive liquid (such as 1.5% glycine) as an irrigant, or as a distension medium to eliminate electrical conduction losses. Glycine is used in isotonic concentrations to prevent osmotic changes in the blood when intra-vascular absorption occurs. In the course of an operation, veins may be severed, with resultant infusion of the liquid into the circulation, which could cause, among other things, a dilution of serum sodium which can lead to a condition known as water intoxication.

Figure 2 is a side view of a portion of an electrosurgical instrument forming part of the system of Figure 1;

Figure 3 is a cross-section of part of an alternative electrosurgical instrument in accordance with the invention, the instrument being sectioned along a longitudinal axis;

Figure 4 is a graph illustrating the hysteresis of the electrical load impedance and dissipated radio frequency power which occurs between use of an instrument in accordance with the invention in desiccating and vaporising modes;

Figure 5 is a block diagram of the generator of the electrosurgical system shown in Figure 1;

Figure 6 is a diagrammatic side view of the instrument of Figure 3 showing the use of the instrument for tissue removal by vaporisation;

Figure 7 is a diagrammatic side view of an instrument similar to that shown in Figure 6, showing the use of the instrument for tissue desiccation or coagulation; and

Figures 8, 9 and 10 are side views of further electrosurgical instruments in accordance with the invention, showing different electrode and insulator configurations.

Referring to the drawings, Figure 1 shows electrosurgical apparatus including an electrosurgical generator 10 having an output socket 10S providing a radio frequency (RF) output for a bipolar instrument, in the form of a handpiece 2 and a detachable electrode unit 28, via a connection cord 14. Activation of the generator 10 may be performed from the handpiece 12 via a control connection in the cord 14, or by means of a footswitch unit 16, as shown, connected separately to the rear of the generator 10 by a footswitch connection cord 18. In the illustrated embodiment, the footswitch unit 16 has two footswitches 16A and 16B for selecting a desiccation mode and a vaporisation mode of the generator 10 respectively. The generator front panel has push buttons 20 and 22 for

very much greater than that of the exposed active electrode treatment portion. The insulating sheath 30S terminates at a location proximally spaced from the distal end of the return electrode 38 in order to provide the required surface area for the return electrode fluid contact surface. At the distal end of the electrode unit, the diameter of the return conductor is typically in the region of from 1mm to 5mm. The longitudinal extent of the exposed part fluid contact surface the return electrode 38 is typically between 1mm and 5mm with the longitudinal spacing from the return electrode 38 to the exposed active electrode treatment portion between 1mm and 5mm. Further aspects of the configuration and dimensioning of electrode assemblies are set out in more detail below.

In effect, the electrode structure shown in Figure 2 is bipolar, with only one of the electrodes (34) actually extending to the distal end of the unit. This means that, in normal use when the electrode assembly is immersed in a conductive fluid medium, the return electrode 38 remains spaced from the tissue being treated and a current path exists between the two electrodes via the tissue and the conductive fluid medium which is in contact with the return electrode.

The axial spacing of the electrodes permits a very fine electrode structure in terms of diameter since the insulation path is considerably longer than a bipolar electrode having merely radial spacing between exposed electrode surfaces. This allows higher powers to be used than with conventional electrode structures without causing unwanted arcing, or in the case of electrosurgical cutting or vaporisation treatment, without causing electrode unit damage due to excessive arcing at high temperatures.

The particular staggered arrangement shown affords the surgeon a view of the tissue contact electrode tip, and permits a large range of applied angles with respect to the tissue surface, which is particularly important in the confined spaces typical of endoscopic surgery.

Referring to Figure 3, an alternative electrode unit for detachable fastening to the electrosurgical instrument handpiece 12 shown in Figure 1 comprises a shaft 30, which

the vaporisation mode. When RF power is applied to the electrode assembly 32 the fluid medium heats up. Assuming the fluid medium is normal saline (0.9% w/v), the temperature coefficient of conductivity of the fluid medium is positive, so that the corresponding impedance coefficient is negative. Thus, as power is applied, the impedance initially falls and continues to fall with increasing dissipation power to point "B", at which point the saline in intimate contact with the electrode assembly 32 reaches its boiling point. Small vapour bubbles form on the surface of the active tip 34A and the impedance then starts to rise. After point "B", as power dissipation is increased further, the positive power coefficient of impedance is dominant, so that increasing power now brings about increasing impedance.

As a vapour pocket forms from the vapour bubbles, there is an increase in the power density at the residual electrode/saline interface. There is, however, an exposed area of the active electrode tip 34A not covered by vapour bubbles, and this further stresses the interface, producing more vapour bubbles and thus even higher power density. This is a run-away condition, with an equilibrium point only occurring once the electrode is completely enveloped in vapour. For given set of variables, there is a power threshold before this new equilibrium can be reached (point "C").

The region of the graph between the points "B" and "C", therefore, represents the upper limit of the desiccation mode. Once in the vaporisation equilibrium state, the impedance rapidly increases to around 1000 ohms, with the absolute value depending on the system variables. The vapour pocket is then sustained by discharges across the vapour pocket between the active electrode tip 34A and the vapour/saline interface. The majority of power dissipation occurs within this pocket, with consequent heating of the tip 34A. The amount of energy dissipation, and the size of the pocket, depends on the output voltage. If this is too low, the pocket will not be sustained, and if it is too high the electrode assembly 32 will be destroyed. Thus, in order to prevent destruction of the electrode assembly 32, the power output of the generator must be reduced once the impedance has reached the point "D". It should be noted that, if the power is not reduced at this point, the power/impedance curve will continue to climb and electrode destruction would occur.

and to a threshold-set input 68C of the voltage threshold detector 68 for setting peak RF output voltage limits.

In operation, the microprocessor controller 72 causes power to be applied to the switched mode power supply 66 when electrosurgical power is demanded by the surgeon operating an activation switch arrangement which may be provided on a handpiece or footswitch (see Figure 1). A constant output voltage threshold is set independently of the supply voltage via input 68C according to control settings on the front panel of the generator (see Figure 1). Typically, for desiccation or coagulation the threshold is set at a desiccation threshold value between 150 volts and 200 volts. When a cutting or vaporisation output is required, the threshold is set to a value in the range of from 250 or 300 volts to 600 volts. These voltage values are peak values. Their being peak values means that for desiccation at least it is preferable to have an output RF waveform of low crest factor to give maximum power before the voltage is clamped at the values given. Typically a crest factor of 1.5 or less is achieved.

When the generator is first activated, the status of the control input 60I of the RF oscillator 60 (which is connected to the "on" time control circuit 70) is "on", such that the power switching device which forms the oscillating element of the oscillator 60 is switched on for a maximum conduction period during each oscillation cycle. The power delivered to the load 64 depends partly on the supply voltage applied to the RF oscillator 60 from the switched mode power supply 66 and partly on the load impedance 64. If the supply voltage is sufficiently high, the temperature of the liquid medium surrounding the electrodes of the electrosurgical instrument (or within a gaseous medium, the temperature of liquids contained within the tissue) may rise to such an extent that the liquid medium vaporises, leading to a rapid increase in load impedance and a consequent rapid increase in the applied output voltage across terminals 12. This is an undesirable state of affairs if a desiccation output is required. For this reason, the voltage threshold for a desiccation output is set to cause trigger signals to be sent to the "on" time control circuit 70 and to the switched mode power supply 66 when the threshold is reached. The "on" time control circuit 70 has the effect of virtually instantaneously reducing the "on" time of the RF

32 is introduced into a selected operation site with the active tip 34A adjacent to the tissue to be treated, and with the tissue and the active tip and the return electrode immersed in the saline. The generator is then activated (and cyclically controlled as described above) to supply sufficient power to the electrode assembly 32 to maintain the saline adjacent to the active tip 34A at, or just below, its boiling point without creating a vapour pocket surrounding the active tip. The electrode assembly is manipulated to cause heating and desiccation of the tissue in a required region adjacent to the active tip 34A. The electrode unit can be used for vaporisation in the region of the graph between the point "D" and the dotted line F which constitutes the level below which vaporisation is no longer stable. The upper part of this curve is used for tissue removal by vaporisation. In this mode, a light application of the instrument to the tissue to be treated enables sculpturing and contouring to be carried out.

The electrode assembly 32 preferably has unitary electrodes with a return: active electrode surface area ratio in the range of from 5:1 to 40:1 (that is to say the ratio of the surface areas of the exposed portions of the two electrodes are in this range).

Figure 6 illustrates the use of the electrode unit of Figure 3 for tissue removal by vaporisation, the electrode unit being immersed in conductive fluid 78. Thus, the electrode unit creates a sufficiently high energy density at the active tip 34A to vaporise tissue 80, and to create a vapour pocket 82 surrounding the active tip. The formation of the vapour pocket 82 creates about a 10-fold increase in contact impedance, with a consequent increase in output voltage. Arcs 84 are created in the vapour pocket 82 to complete the circuit to the return electrode 38. Tissue 80 which contacts the vapour pocket 82 will represent a path of least electrical resistance to complete the circuit. The closer the tissue 80 comes to the active tip 34A, the more energy is concentrated to the tissue, to the extent that the cells explode as they are struck by the arcs 84, because the return path through the connective fluid (saline in this case) is blocked by the high impedance barrier of the vapour pocket 82. The saline solution also acts to dissolve or disperse the solid products of vaporisation.

solution, without passing through the tissue. For example, in the embodiment shown in Figure 7, only the distal portion of the active electrode contacts the tissue, with the proximal portion remaining spaced away from the tissue.

The invention can achieve desiccation with no or minimal charring of the tissue. When the active electrode 34 contacts the tissue 80, current passes through the tissue, causing the tissue at and around the contact point to desiccate. The area and volume of desiccated tissue expands generally radially outward from the point of contact.

In the embodiment shown in Figure 7, the exposed treatment portion of the active electrode 34 is longer than it is wide. This allows the electrode tip to contact the tissue surface while still maintaining most of the exposed treatment portion out of contact with the tissue even when the instrument is angled with respect to the tissue surface. Because most of the exposed portion of the electrode is out of contact with the tissue, the current path will more easily shift, upon desiccation of a sufficient tissue volume, from the path through the tissue to a path that goes directly from the active electrode to the saline solution.

In the electrode unit shown in Figure 3 the exposed portion of the active electrode 34 is relatively short compared with the length of the insulation member 36 between the active electrode 34 and the return electrode 38. With such an electrode configuration, bistable operation of the instrument inherent in the hysteresis characteristic described above with reference to Figure 4 applies, in that the instrument can be used in a desiccation mode or in a low power vaporisation mode. In some circumstances, particularly if the exposed treatment portion of the active electrode is long, bistable operation may be difficult to achieve.

Measures to overcome this difficulty will now be described with reference to Figure 8 which shows an electrode unit comprising a shaft 30 constituted by a semi-flexible tube made of stainless steel or phynox electroplated in copper or gold, with an electrode assembly 32 at a distal end thereof. The electrode assembly 32 includes a central active

minimum path length is, in the case of the embodiment shown in Figure 8, the length *a* of the sleeve 36 plus the step radius *c*, as shown in Figure 8.

A further consideration is the possibility of a vapour pocket forming only over part of the exposed treatment portion 34A of the active electrode 34. When the applied voltage and power are sufficiently high, a vapour pocket will form around the active electrode exposed treatment portion. Preferably, the pocket is formed uniformly over the entire length of the treatment portion. In such a situation, the load impedance presented to the generator can change by as much as a factor of 20. However, when there are significant differences in the conduction path length between the return electrode fluid contact surface and different parts of the exposed active electrode treatment portion 34A, a voltage gradient is established over the length of each electrode. Preferably, the fluid contact surface is large enough and has an aspect ratio such that its length is at least as great as its diameter so as to minimise a voltage gradient over its surface. Nevertheless, with some insulation sleeve and active electrode configurations, the voltage gradient can be sufficiently large to enable vapour pocket formation only over that part of the exposed treatment portion closest to the fluid contact surface, leaving the extreme distal end of the exposed treatment portion still in contact with the conductive fluid. Thus, the voltage gradient is established within the conductive fluid where the edge of the vapour pocket intersects the surface of the active electrode treatment portion 34A. The electrical behaviour of such a partially enveloped active electrode treatment portion is very different from that of a fully enveloped treatment portion. The impedance transition from the wetted state to the vapour enveloped state is far less marked than described above with reference to Figure 4. In terms of controlling generator output by sensing peak voltage, the behaviour of the electrode assembly is no longer bistable. However, the power demand is considerably higher as a result of the vaporisation voltage presented across the low impedance wetted region of the active electrode treatment portion. The clinical effect is not only the required vaporisation, but also an undesirable thermal damaging effect resulting from the increased power dissipation.

which the instrument may be introduced towards the tissue, the return electrode 38 being set back in the direction of the treatment axis from the active electrode 34A. For the purpose of comparing the different conduction path lengths between the return electrode and different parts of the active electrode treatment portion, paths in a common plane should be considered, the plane containing the treatment axis 42. In the case of the views of Figures 8, 9 and 10, the illustrated path lengths are, of course, in the plane of the paper bearing the views.

3. An instrument according to claim 1, wherein the first direction defines a treatment axis and said two shortest conduction paths (P_1, P_2) lie in a common plane containing the treatment axis.

4. An instrument according to claim 1, wherein the length of said shortest conduction path (P_2) through the fluid medium between the exposed fluid contact surface and the exposed treatment portion is at least 1mm.

5. An instrument according to claim 1, wherein the exposed fluid contact surface is generally cylindrical and has a length and a diameter, the length of the fluid contact surface being at least as great as its diameter and wherein the ratio of (i) the shortest conduction path (P_1) through the fluid medium between the fluid contact surface and that part of the exposed treatment portion which is furthest from the fluid contact surface, to (ii) the fluid contact surface diameter, is at most 4.5 to 1.

6. An instrument according to claim 1, wherein the ratio of (i) the length of the shortest conduction path (P_1) through the fluid medium between the exposed fluid contact surface and that part of the exposed treatment portion which is furthest from the exposed fluid contact surface, to (ii) the length of the shortest conduction path (P_2) through the fluid medium between the exposed fluid contact surface and the exposed treatment portion, is greater than or equal to 1.25. .

7. An electrosurgical system according to claim 1, further comprising an electrosurgical generator for supplying radio frequency power to the instrument, the generator including an output stage having at least a pair of electrosurgical output connections connectible respectively to the active electrode and the return electrode of the instrument, a sensing circuit for deriving a sensing signal representative of the peak radio frequency output voltage developed between the output connections, and a power adjustment circuit for automatically causing a

a return electrode having a fluid contact surface set back from the treatment portion of the active electrode and spaced from the treatment portion by an insulation member such that when the treatment portion is bought adjacent a tissue surface immersed in the fluid medium the fluid contact surface is normally spaced from the tissue surface and the fluid medium completes a conduction path between the active electrode and the return electrode.

13. An instrument according to claim 12, wherein the return electrode comprises a conductive sleeve located around the insulation member behind the treatment portion of the active electrode.

14. An instrument according to claim 12, wherein the treatment portion of the active electrode is located at an extreme distal end of the assembly and the fluid contact surface of the return electrode is spaced proximally from the active electrode treatment portion, and wherein the exposed portion of the active electrode has a length and a width, the length being greater than at least one half of the width.

15. An instrument according to claim 14, wherein the longitudinal spacing of the active electrode exposed portion and the return electrode fluid contact surface is at least 1mm.

16. An instrument according to claim 15, wherein the ratio of (i) the longitudinal distance between the distal end of the active electrode exposed portion and the most distal part of the return electrode, to (ii) the shortest longitudinal distance between the active electrode exposed portion and the most distal part of the return electrode, is less than or equal to 2 to 1.

17. An instrument according to claim 15 or claim 16, wherein the return electrode has a fluid contact surface encircling the insulation member and wherein the ratio of (i) the longitudinal distance between the distal end of the active electrode exposed portion and the distal edge of the fluid contact surface of the return electrode to (ii)

22. An instrument according to claim 19, wherein the active electrode treatment interface comprises a conductive active electrode tip member the length of which is the outward direction is at least one half of its width, and wherein the insulation member has an end face adjacent the tip member, which face does not extend laterally beyond said tip member by more than one half of said tip member length.

23. An electrosurgical instrument for the treatment of tissue in the presence of an electrically conductive fluid medium, the instrument comprising:

an instrument shaft, and

an electrode assembly at a distal end of the shaft, the electrode assembly having a distal end and including an active electrode and a return electrode, with an exposed portion of the active electrode at the distal end of the electrode assembly and a fluid contact surface of the return electrode positioned proximally of the active electrode exposed portion, further including an insulating member positioned between and electrically insulating the active electrode and the return electrode, wherein the exposed portion of the active electrode has a length and a width, and the length of the active electrode exposed portion is greater than the width of the active electrode exposed portion.

24. An instrument according to claim 23, wherein the exposed portion of the active electrode extends longitudinally from the distal end of the shaft.

25. An instrument according to claim 23, wherein the insulation member comprises a generally cylindrical sleeve and the return electrode is located on the outside of the sleeve longitudinally spaced from the exposed portion of the active electrode by a distance of at least 1mm.

26. An instrument according to claim 25, wherein the insulation member has an annular distal end face defining a shoulder, and the active electrode exposed portion is centrally located with respect to and projects from the insulation member end face, the depth of the shoulder in a direction laterally away from the

contact surface spaced and set back from the exposed treatment portion, the method comprising the steps of:

(a) introducing the electrode assembly into a selected operation site;

(b) surrounding the electrode assembly with a conductive fluid so that the conductive fluid defines an electrical path between the active and return electrodes;

(c) applying sufficient radio frequency output power to the electrode assembly to increase the temperature of the conductive fluid adjacent the active electrode treatment portion without creating a vapour pocket surrounding the treatment portion;

(d) contacting the treatment portion to tissue while maintaining the return electrode fluid contact surface out of contact with the tissue.

32. The method of claim 31, wherein step (d) includes maintaining a part of the exposed treatment portion of the active electrode out of contact with the tissue.

33. The method of claim 32, wherein step (d) includes the further step of:

(e) moving the active electrode across a surface of the tissue.

34. The method of claim 33, wherein step (e) includes moving the electrode across the tissue surface in a side-to-side motion.

35. The method of claim 31, wherein step (c) includes maintaining the temperature of the conductive fluid adjacent to the active electrode treatment portion substantially at the boiling point of the conductive fluid.

36. The method of claim 31, wherein the conductive fluid comprises a saline solution.

37. The method of claim 31, wherein the conductive fluid comprises a compound sodium lactate solution.

positioning a part of the exposed treatment portion adjacent and from time to time in contact with the tissue.

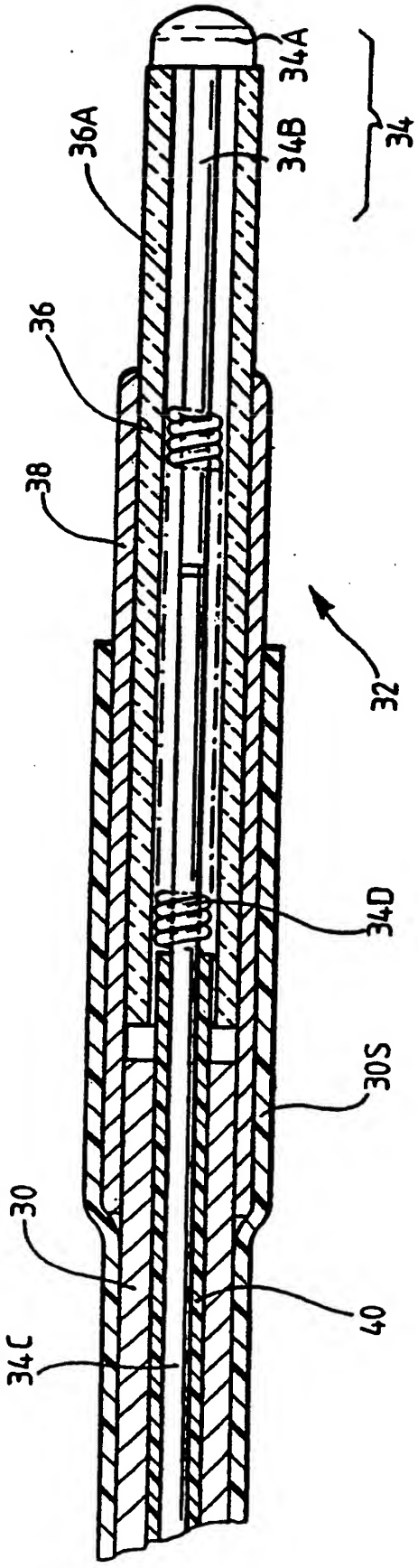
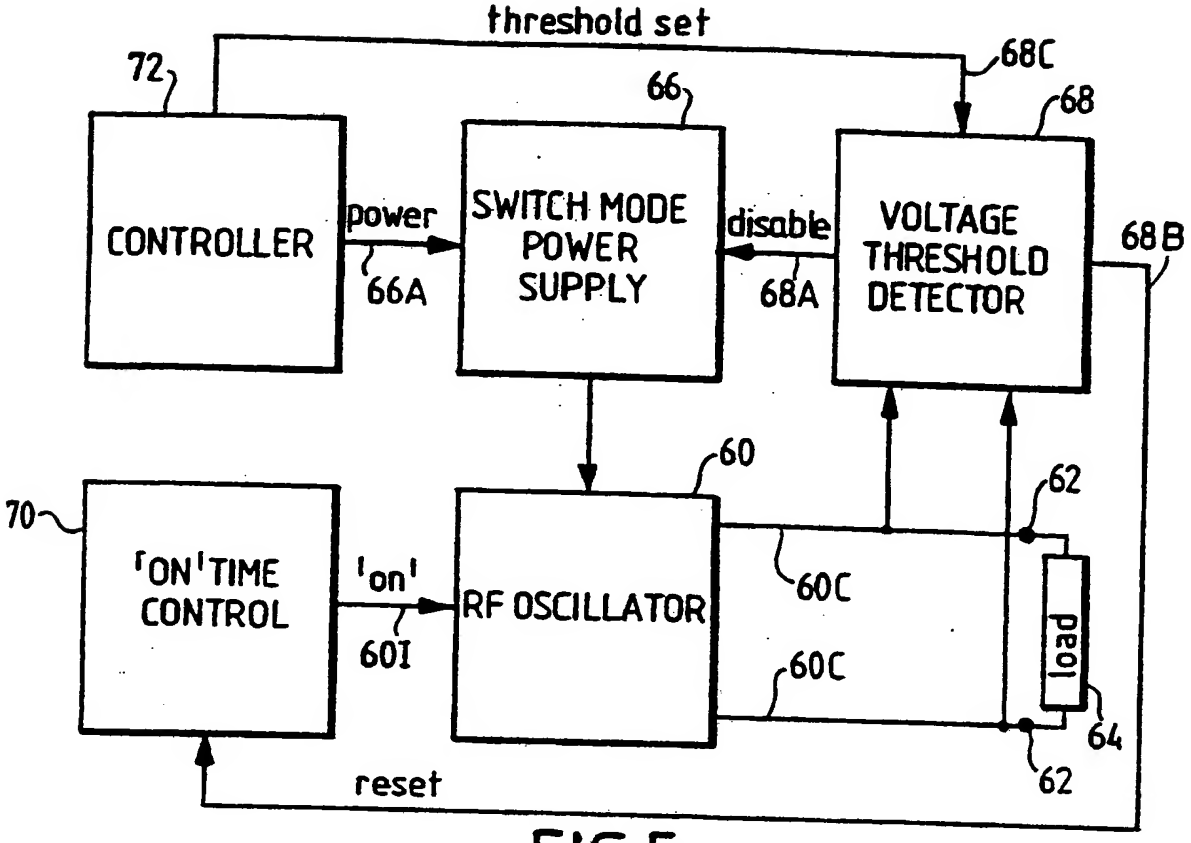


FIG.3.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VOLTAGE THRESHOLD DETECTOR
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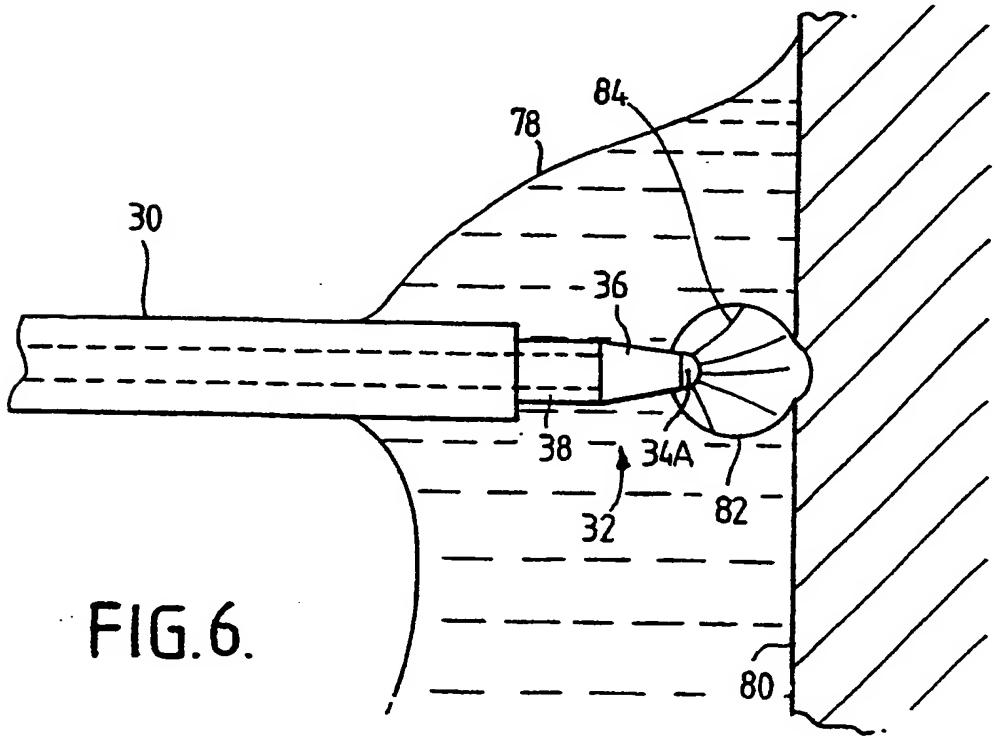
FIG.5.


84
78
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36
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34A
82
32
80

FIG.6.

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/GB 96/01473

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,93 19681 (VALLEYLAB) 14 October 1993 see page 4, line 14 - line 18	1,12,19
A	US,A,5 261 906 (PENNINO) 16 November 1993 see abstract; figures 1-9	1
A	US,A,4 706 667 (ROOS) 17 November 1987 cited in the application see abstract	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
8 October 1996	14. 10. 96

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Papone, F

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int ional Application No
PCT/GB 96/01473

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